REMARKS

Claims 1, 3-15, 32-33, and 35-37 remain pending in the application. Claims 1, 3-4, 13-14, and 35-37 stand rejected under 35 U.S.C. § 102(e) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Publication No. 2005/0039745 to Stahmann et al. ("Stahmann"). Claims 5-6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stahmann in view of U.S. Patent No. 5,540,733 to Testerman ("Testerman"). Claims 7-8, 15, and 32-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stahmann in view of U.S. Patent No. 5,207,230 to Bowers ("Bowers"). Claims 9-12 stand rejected 35 U.S.C. § 103(a) as being unpatentable over Stahmann and Bowers in view of U.S. Publication No. 2002/0049479 to Pitts ("Pitts"). Testerman, Bowers, and Pitts were all previously cited 1) in a January 2009 Office Action, to which Applicants responded in April 2009, and again 2) in a June 2009 Office Action, to which Applicants responded in August 2009. Claims 1, 7, 15, and 35-37 are being amended to clarify the calculation and comparison potions of the claims.

The present invention is directed to an implantable device and methods of treating sleep disordered breathing with the implantable device, wherein the device includes a detector to detect changes in transthoracic impedance, a stimulator, a real time clock, and a postural sensor. The treatment is in the form of electrical or mechanical stimulation of afferent nerves. All of the methods of the present invention include detecting aspects of a patient's real time condition and providing two different modes of stimulation, with the mode of stimulation based upon the patient's detected condition. In the methods of the present invention, the sleep

state of the patient is initially determined based at least in part on both the real time clock and the postural sensor. Once the patient is determined to be asleep (and not when an obstruction is determined to be present), stimulation is provided prophylactically so as to prevent airway collapse or to increase tone of upper airway muscles (Mode I). Importantly, none of the references cited in the Office Action determine the patient's sleep state using this method. Some of the cited references do not determine the patient's sleep state at all and none use the product's sleep state as a trigger for when to provide stimulation. Further, none of the cited references disclose or suggest providing prophylactic stimulation.

The detector of the device of the present invention also emits additional high frequency pulses, detects transthoracic impedance consequential to the pulses, and determines changes to the transthoracic impedance which are indicative of an obstruction. If an obstruction is determined to be present, the stimulation is increased (Mode II).

All claims stand rejected, at least in part, based upon Stahmann. However, Stahmann teaches something completely different from the present invention. Stahmann teaches an approach for providing therapy whereby the therapy 1) is initially provided based on detecting disordered breathing and then 2) adapted based upon its effectiveness. "An approach to providing disordered breathing therapy includes detecting disordered breathing and adapting a therapy to mitigate the disordered breathing." (Stahmann Abstract). Stahmann does not disclose or suggest determining a patient's sleep state for the purpose of commencing therapy. Stahmann also does not disclose or suggest determining a patient's

sleep state using a real time clock in combination with a postural sensor. With reference to Stahmann Fig. 2, Stahmann determines the presence of a disordered breathing episode 220 before delivering therapy 230. Similarly, with reference to Fig. 3, Stahmann determines the presence of a disordered breathing episode 320 before delivering therapy 330. Stahmann does not commence therapy in advance of detecting an obstruction and even states that its method "involves detecting disordered breathing." (¶ 0006). Stahmann is not at all directed to using the patient's sleep state as a trigger to commence therapy so as to avoid obstructions developing or to providing therapy prophylactically at all. Further, although Table 1 of Stahmann provides dozens of examples of patient conditions, these are described as conditions in connection with disordered breathing (¶ 0043). The examples in the table are not described as conditions used as triggers for commencing prophylactic therapy or for providing prophylactic therapy at all. The table and the disclosure as a whole do not disclose or suggest detecting the patient's sleep state as a basis for starting or providing therapy. Further, in the present invention, the detection of sleep state is unrelated to detecting disordered breathing, which is achieved in a completed different way. In summary, Stahmann teaches delivering therapy based on detecting an obstruction and it does not teach delivering therapy prophylactically based upon the patient's sleep state nor does it teach delivering therapy in the absence of disordered breathing.

Further, Stahmann's implantable device is completely different from the implantable device of the present invention in that Stahmann's device does not include either a real time clock or a postural sensor.

With regard to the Examiner's reference to Stahmann ¶ 0046 in which the Examiner asserts that Stahmann determined the likelihood that the patient is asleep, 1) Stahmann does not teach the present method of determining the patient's sleep state as articulated in the claims and 2) Stahmann merely teaches to confirming the patient's sleep state (presumably for patients who have devices that falsely record obstructions outside of sleep) but still bases providing therapy on the presence of an obstruction. As previously stated, in the present invention, sleep state is the determining factor for commencing therapy.

With regard to the type of treatment being provided, the present invention initially provides treatment to prevent airway collapse (see specifically claims 1, 7, 15, and 35-37). In contrast, Stahmann only refers to specific events of overcoming tongue prolapse by "electrical activation of the tongue muscles" or overcoming cardiac pacing events. (see ¶ 0032-0033). The method of treatment of the present invention for preventing airway collapse is to stimulate afferent nerves (for example, see claim 1).

Stahmann's method of providing and subsequently increasing treatment is completely different than the method of the present invention and the trigger for increasing treatment is different as well. In the present invention, treatment is initially delivered prophylactically upon determining that the patient is asleep. After treatment is initiated, the presence of an obstruction is determined. Only when it is determined that an obstruction is present is treatment increased. In contrast, Stahmann delivers initial treatment only following detection of a disordered breathing episode. (see, for example, FIG. 2, steps 220, 230). Only when the

treatment is not considered effective (for example, FIG. 2, steps 250, 270) is treatment increased. Because the method and trigger of the present invention are completely different from those of Stahmann and are not disclosed or suggested by Stahmann, Stahmann does not anticipate the present invention and does not otherwise make the present invention unpatentable.

Further, the apparatus claims of the present invention (claims 35-37) are not disclosed or suggested by Stahmann. Several elements of the apparatus, such as the detector, the real time clock, and the postural sensor, and not disclosed or suggested as being incorporated in an implantable device.

According to paragraph 4 of the Office Action, Stahmann FIGs. 2 and 3 and ¶ 0086 disclose a real time clock. The Applicants respectfully disagree. Nothing in FIGs. 2 or 3 or ¶ 0086 suggest a real time clock, implantable or otherwise. Paragraph 0086 suggests real time monitoring, which is completely different from the present invention's implantable device, which includes a real time clock. Real time monitoring may be external to the device and may not include a clock or any measure of time. In actuality, Stahmann makes no mention of measuring time. At the end of paragraph 4 of the Office Action, the Examiner also cites to Stahmann ¶¶ 0040, 0058, and 0112. However none of these refer to a real time clock either.

Paragraph 4 of the Office Action includes a reference to Stahmann ¶ 0101 for teaching to comparing an instantaneous signal to a recent average of instantaneous transthoracic impedance signals. However, Applicants disagree because Stahmann includes no disclosure for comparing instantaneous transthoracic impedance to a recent average. Paragraph 0101 only describes

"monitoring the respiratory waveform output of the transthoracic impedance senor" without disclosing any methodology for doing so. Although paragraph 0101 also discloses a methodology regarding determining a hypopnea based upon tidal volume measurements, this disclosure is outside the scope of the present invention.

Also, according to the Office Action, Stahmann ¶ 0044 discloses a detector to detect transthoracic impedance changes. However, Stahmann does not disclose any method for such detection and the present invention details a specific method, not even mentioned by Stahmann, for detecting transthoracic impedance changes, including emitting high frequency pulses, calculating instantaneous transthoracic impedance, and comparing the instantaneous transthoracic impedance to a recent average. In paragraph 5 of the Office Action, the Examiner states that using "high frequency" electrical pulses to determine transthoracic impedance would be obvious to one of ordinary skill in the art. The Applicants disagree that the method used in the present invention for applying electrical pulses – that is, further calculating instantaneous transthoracic impedance and comparing it to a recent average – either alone or in combination with the other articulated steps is obvious and the Office Action does not indicate that the process in its entirety is obvious. In addition, even if it were obvious, the use of electrical pulses is one step in a much larger process and, based on the numerous points raised in this response, that larger process is not obvious over Stahmann or Stahmann in combination with the other cited references.

Paragraph 5 of the Office Action also includes a rejection of claim 3 based on the site of electrical stimulation being disclosed in Stahmann ¶ 0032. However, for the reasons articulated above, numerous steps of claim 1, on which claim 3 depends, are not anticipated or made obvious by Stahmann.

With regard to the rejection of claims 5 and 6 (Office Action paragraphs 6-8), which depend from claim 1, the Examiner primarily relies on Stahmann and further relies on Testerman for disclosing the limitation that the electrical stimulation is comprised of a train of electrical pulses, the Examiner arguing that it would be obvious to use a train of pulses in order to extend battery life. But as detailed above, Stahmann does not disclose or suggest several steps in the method of claim 1. In addition, although Testerman may discuss trains of pulses, such discussion is clearly not in the context of the present invention. Testerman does not disclose an implantable device with any real time clock or even use of time of day. Testerman also does not determine whether the patient is asleep by combined use of time and a postural sensor. Testerman's device needs to be activated before the patient is asleep by use of a power-on reset or manual reset. Testerman assumes a sleep state once a predetermined time period expires after the device is turned on. Once turned on, the device in Testerman imposes a delay before starting any stimulation, whereas the present invention does not require a time delay. Further, Testerman does not disclose starting stimulation in response to the patient being asleep but rather only after (1) the device is turned on, (2) a prescribed delay has taken place, and (3) the presence of an "event" has been determined. (see col. 15, ln. 9-16). In Testerman, all three of the aforementioned

conditions must be satisfied before stimulation is provided. Furthermore, Testerman's method for determining the presence of an event is nothing like the change in thoracic impedance method of the present invention. Testerman determines the onset of an event by "monitoring changes in respiratory effort waveform" based upon "averag[ing] over successive respiratory cycles." (see Testerman Abstract). Also, because Testerman only discloses beginning stimulation upon determining the presence of an event, it does not disclose the bi-modal approach of the present invention or prophylactically providing stimulation. Testerman does not disclose or suggest any kind of bi-modal operation, much less that of Applicants. Also, Testerman does not measure transthoracic impedance (or differences in transthoracic impedance) at all, let alone to determine the onset of an event, nor does Testerman transmit high frequency pulses so as to detect transthoracic impedance change. Because Testerman is directed to something completely different from the present invention and Testerman does not disclose or suggest limitations found in the present invention (and neither does Stahmann). Testerman, in combination with Stahmann, does not preclude patentability of claim 5.

In addition, with regard to claim 6, the Examiner states that it would be obvious to use a 10-30 pulse train length. (¶ 6, citing In re Aller, 105 U.S.P.Q. 233). However, claim 6 depends from claims 1 and 5 and because claims 1 and 5 are believed to be in condition for allowance for the reasons previously discussed, claim 6 should similarly be allowable.

In summary, there is no suggestion in either Testerman or Stahmann to include trains of pulses with the other limitations of the present invention.

Claims 7-8, 15 and 32-33 are rejected, at least in part, based on the combination of Stahmann and Bowers (Office Action paragraphs 9-10). The Examiner relies upon Bowers (col. 3, ln. 20-23, and col. 10, ln. 25-30) for the step of mechanical stimulation of nerves to increase muscle tone to reject claims 7-12 and 32-33 and for the mechanical stimulation element of claim 15. However, as detailed in Applicant's April 2009 and Applicant's August 2009 correspondence, Bowers is directed to a sensor with a transducer film which attaches to a body portion to record mechanical forces or potentially to provide stimulation. Unlike the present invention, Bowers does not disclose or even discuss nerve stimulation to increase muscle tone, nor does Bowers disclose or suggest numerous elements of the claims of the present invention. Bowers does not determine the sleep state of the patient in any way. Bowers does not disclose bi-modal use at all and, in particular, does not disclose bi-model use as detailed in the claims of the present invention. Bowers also does not determine the onset of an obstruction. More broadly, Bowers does not disclose or suggest the use of a sensor or any other device to treat sleep disorders. Further, Bowers does not suggest sensing changes in transthoracic impedance. In short, Bowers discloses a piezo-mechanical device but does not, alone or in combination with Stahmann, disclose or suggest use of a piezo-mechanical element in an implantable device such as in the present invention nor does it disclose or suggest the methods of the present invention. There also is no suggestion in Bowers to include mechanical stimulation

in combination with the limitations of the present invention, just as Stahmann does not disclose or suggest the limitations of the present invention and does not disclose or suggest adding mechanical stimulation of nerves.

The Examiner relies in part on Pitts in combination with Stahmann and Bowers to reject claims 9-12 (Office Action paragraphs 11-12). Regarding claim 9, the Examiner relies on Pitts solely based upon Pitts' disclosing a piezo-electric mechanical element implanted within or adjacent to the base of the genioglossus muscle. However, as previously detailed above, neither Stahmann nor Bowers discloses or suggests several limitations of the present invention. Also, Pitts does not disclose or suggest those same limitations and Pitts does not disclose or suggest implanting the device in combination with the other limitations of the present invention. For example, the Pitts' device does not include a real time clock, a postural sensor, or a detector to detect changes in thoracic impedance. Pitts also does not provide bi-modal stimulation as defined in the present claims. In Pitts, the only stimulation is a low level stimulation and Pitts does not describe any increase or change in stimulation. Further, Pitts does not disclose how it determines the patient's sleep state other than "[t]he device(s) is turned on as the patient goes to bed." (¶ 0030). Pitts does not disclose a real time clock. The Pitts reference to "selected time of day" is not a disclosure or suggestion to use a real time clock and Pitts does not disclose or suggest that a clock and postural sensor are housed within an implantable device and used together for detecting a patient's sleep state. Without a real time clock or position sensor, the method of Pitts

cannot be the method of the present invention. Finally, Pitts does not even disclose determining the presence of an obstruction.

With regard to the rejection of claims 10-11, the Examiner relies in part on Bowers (col. 10, ln. 25-30) and Pitts (¶ 0029) for disclosing that the duration of mechanical stimulation is on the order of several seconds of vibration. However, Bowers col. 10, ln. 25-30 says nothing as to duration of stimulation. With regard to the rejection of claim 12, the Examiner relies on Pitts (¶ 0029) for disclosing the frequency range of mechanical vibration. The cited passage in Bowers merely refers to applying a low frequency vibration to induce sleep and the benefit of mechanical stimulation as compared with electrical stimulation. Similarly the cited passage of Pitts does not refer to duration of stimulation either. Pitts ¶ 0029 merely refers to repetitive stimulation. Further, Pitts was cited in earlier Office Actions and Applicant's April 14, 2009 and August 17, 2009 responses detail the inapplicability of Pitts as a reference. In addition to the reasons detailed above regarding Bowers and Stahmann not disclosing or suggesting limitations of the present invention, neither Bowers nor Pitts together with Stahmann discloses or suggests the combination of limitations of the present invention. In summary, with regard to claims 9-12, the entirety of the limitations is not disclosed or suggested in Stahmann combined with Bowers and Pitts.

In summary, even when combining Stahmann, Testerman, Bowers, and Pitts, in any combination, several features of the present invention which are not disclosed or suggested include an implantable device with all the claimed elements, including bi-modal stimulation, determining the presence of an

obstruction, and determining the patient's sleep state. As a result, it is believed that claims 1, 3-15, 32-33, and 35-37 are in condition for allowance.

The allowance of claims 1, 3-15, 32-33, and 35-37 and the early passage to issue of the application are respectfully requested.

Respectfully submitted,
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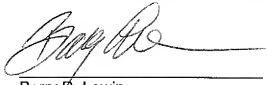

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